UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

UNITED STATES OF AMERICA, and STATE OF NEW MEXICO, *ex. rel.*	
SALLY HANSEN, Relator;	
Plaintiffs,	**No. _____**
v.	**FILED UNDER SEAL AND IN CAMERA**
DEMING HOSPITAL CORPORATION d/b/a MIMBRES MEMORIAL HOSPITAL, COMMUNITY HEALTH SYSTEMS, INC., COMMUNITY HEALTH SYSTEMS PROFESSIONAL SERVICES CORP., and JERRY BESSELL,	**COMPLAINT**
	JURY TRIAL DEMANDED
Defendants.	

COMPLAINT

The United States of America and the State of New Mexico, on relation of Sally Hansen ("Hansen" or "Relator"), complain against Defendants Deming Hospital Corporation d/b/a/ Mimbres Memorial Hospital ("Mimbres" or "MMH"), Community Health Systems, Inc. ("CHS"), Community Health Systems Professional Services Corp., and Jerry Bessell ("Bessell") (collectively, "Defendants") as follows:

NATURE OF THE CASE

1. This is a *qui tam* action pursuant to the federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, the New Mexico Medicaid False Claims Act, New Mexico Statutes § 27-14-1, *et seq.*, and the New Mexico Fraud Against Taxpayers Act, New Mexico Statutes § 44-9-1, *et seq.* This action seeks to recover damages and penalties against Defendants for causing claims to be submitted to Medicare and the New Mexico Medicaid program for the improper reimbursement

of laboratory tests and related services performed in the Mimbres Lab for which quality control procedures required under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") were not performed. This action also seeks damages stemming from Defendants' retaliatory treatment of Relator for investigating and raising concerns about the violations discussed herein.

2. The Centers for Medicare and Medicaid Services ("CMS") regulates all lab testing performed on humans in the United States through CLIA. The objective of CLIA is to ensure the accuracy, reliability and safety of laboratory testing through the adoption of certain minimum testing standards across all laboratories. It sets forth comprehensive quality requirements: laboratories must, *inter alia*, 1) use materials that provide accurate and reliable test results and act in accordance with performance specifications, 2) maintain a written procedures manual, 3) perform maintenance and function checks as specified by the manufacturer of equipment and instruments, 4) ensure equipment is calibrated and verified according to manufacturer instructions, and 5) employ personnel that meet certain educational and work experience standards.

3. Defendants operate Mimbres Memorial Hospital, an acute care hospital in Southwest New Mexico. Mimbres has an in-house medical laboratory that provides comprehensive laboratory and transfusion services in support of diagnosis and treatment of inpatients and outpatients. Approximately 80 percent of all medical diagnoses involve some type of lab testing.

4. Medical providers such as Mimbres are allowed to bill for lab services performed in connection with patient care. However, in order to obtain reimbursements from Medicare and Medicaid for lab services, a medical lab must maintain CLIA certification and perform lab

testing in accordance with CLIA requirements. Lab services that are performed in violation of CLIA are ineligible for reimbursement.

5. Immediately upon starting at Mimbres as a Medical Technologist in May 2010, Relator observed that Mimbres was in blatant violation of CLIA requirements concerning lab testing and that the violations placed patients' lives in grave danger. Specifically, Mimbres failed to conduct routine quality control procedures on instruments and equipment, from complex microbiology analyzers to commonly-used testing media such as agar plates, and on processes used during laboratory testing. Because of these violations, the accuracy of lab results produced in Mimbres' lab could not be validated or verified. Mimbres knew that these results would form the basis of diagnosis and treatment decisions by physicians and other practitioners, but ignored the risks to patient health and safety from this conduct.

6. Relator brought her concerns about CLIA violations to the Lab Director and other Mimbres officials, and then to the Chief Executive Officer. No actions were taken to improve lab procedures to bring them into compliance with CLIA; rather, the Lab Director and another Medical Technologist threatened and harassed her, and pressured her to quit. When she did not, she was placed on administrative leave in retaliation for raising her concerns.

7. While Relator was on administrative leave, a compliance official finally conducted an investigation into her allegations of CLIA violations in Mimbres' lab and found that she was right. The violations were so bad that the microbiology department within the lab was shut down.

8. In addition to threatening patient safety, Defendants' conduct violated the False Claims Act and similar state laws. Despite the knowledge that Mimbres was violating CLIA,

Defendants nevertheless billed Medicare and Medicaid for ineligible lab services provided in support of the treatment of Medicare and Medicaid patients. As a result, Defendants submitted and caused to be submitted false claims to the United States and the State of New Mexico.

9. Relator also brings a claim for retaliation in that she was threatened, harassed, and ultimately placed on administrative leave because she raised concerns about, and refused to participate in, Defendants' fraudulent conduct.

10. Relator brings this action to recover damages suffered by the United States and New Mexico and to prevent future misconduct by Defendants.

PARTIES AND RELEVANT PERSONS

11. Relator Sally Hansen is a citizen and resident of New Mexico. Relator began working for defendants on or about May 24, 2010 as a Medical Technologist. She received her Bachelor of Science degree in Medical Technology from Oregon Health Sciences University in 1997. She has worked as a Medical Technologist for 14 years, including three years in the specialty of Microbiology.

12. Defendant Community Health Systems, Inc. is the largest publicly-traded operator of hospitals in the United States. As of December 31, 2010, CHS owned, operated or leased 130 hospitals in 29 states, with an aggregate of approximately 19,400 licensed beds. For the fiscal year that ended December 31, 2010, CHS generated almost $13 billion in revenues.

13. CHS is a publicly-traded company, incorporated under the laws of the State of Delaware, headquartered at 4000 Meridian Boulevard, Brentwood, Tennessee 37067. It trades on the New York Stock Exchange under the symbol "CYH." CHS is the parent company of

Defendant Deming Hospital Corporation, through which it owns and operates Mimbres Memorial Hospital.

14. Defendant Community Health Systems Professional Services Corporation is a Delaware corporation also located at 4000 Meridian Boulevard, Brentwood, Tennessee 37067, and is an affiliate of Defendant CHS. It provides management services for Mimbres Memorial Hospital.

15. Defendant Deming Hospital Corporation d/b/a Mimbres Memorial Hospital is a CHS-affiliated acute care hospital located at 900 West Ash Street, Deming, New Mexico 88030. Mimbres provides a full range of medical services to patients including Medicare and Medicaid enrollees.

16. Defendant Jerry Bessell was, at all relevant times herein, the Lab Director for the Mimbres medical laboratory. He was responsible for signing off on the laboratory Procedures Manual and was ultimately responsible for ensuring the laboratory procedures and practices conformed to CLIA requirements.

17. Rene Rivero ("Rivero") was, at all relevant times herein, a Medical Technologist in the microbiology department at Mimbres. He worked as a Medical Technologist since approximately January 2008. Rivero had put in place many of the practices and procedures in the microbiology lab, and was involved in training and supervising microbiology lab personnel.

JURISDICTION AND VENUE

18. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 because the case arises under a federal statute, 31 U.S.C. § 3729, *et seq*.

19. This Court has jurisdiction over Relator's state claims pursuant to 28 U.S.C. § 1367 and 31 U.S.C. § 3732(b).

20. Venue is proper because Defendants transact business in this District. 31 U.S.C. § 3732(a).

21. There has been no public disclosure of the fraud alleged herein, and Relator is an original source of the information. Relator has direct and independent knowledge of the fraud through her work at Mimbres.

ADDITIONAL FACTS

22. Approximately 50% of Defendants' revenues generated at Mimbres are from Medicare and Medicaid. The percentage of Medicare and Medicaid patients is significantly greater.

23. CLIA was enacted in 1988 in response to public health concerns over largely unregulated laboratory services. CLIA sought to address concerns about the unreliability of lab test results, and in particular about false and negative Pap smears that caused cervical cancer to go undiagnosed in many women. CLIA required the implementation of adequate standards across all laboratories to eliminate missed diagnoses and to reduce health care costs associated with such errors.

24. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations, has the responsibility for implementing CLIA. All clinical laboratories must be properly certified to receive Medicare or Medicaid payments.

25. CLIA certification inspections occur every two years and are performed by inspectors from agencies trained by CMS, or by approved accrediting organizations such as The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"). Certification inspectors may tour lab facilities, observe testing, interview lab employees, and review records to evaluate, among other things, lab compliance with quality control requirements for maintaining instruments and equipment and conducting and validating analytical testing.

26. For each specialty and subspecialty within a laboratory, regulations enacted under CLIA set forth detailed quality control requirements, including the frequency and scope of quality testing to ensure that equipment, instruments and materials are functioning properly.

27. Mimbres' laboratory is subject to CLIA and is certified to conduct lab testing in the specialties of Microbiology, Hematology, Chemistry, Serology, Coagulation Studies, Urinalysis, and Blood Bank/Transfusion Services. Some specialties contain sub-specialties, each of which can be subject to additional CLIA regulations. For example, the specialty of Microbiology, which is focused on identifying pathogenic microorganisms in the human body (such as bacteria and fungi) for diagnosis and treatment, includes the subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology.

28. When Relator joined Mimbres in May 2010, she immediately observed numerous CLIA violations in the microbiology lab.

29. The lab's Procedures Manual was woefully inadequate and out of date: it included instructions for equipment and procedures that were no longer in use, and did not include instructions for newer equipment and procedures used regularly. For example, it included

instructions for use of a blood culture analyzer and culture media that were no longer in use but not for a newer analyzer and media in use at the time. In addition, Mimbres did not have controls in place, such as monitoring and periodic internal reviews, to ensure that aspects of the Procedures Manual that were still relevant and applicable were actually followed and that such testing was documented.

30. Under CLIA, laboratories are required to establish and follow written policies and procedures, and to document all tests performed by the laboratory. For each test procedure, the procedure manual must include requirements for patient preparation, specimen collection, storage, preservation, transportation, and processing, as well as step-by-step instructions for performing the procedure and interpreting the results. In addition, the procedure manual must include instructions for preparing slides, solutions and other materials used in testing, and setting forth calibration procedures and acceptable ranges for test results. Under CLIA, the laboratory director is responsible for maintaining the procedure manual, as well as ensuring the overall operation and administration of the laboratory. See, e.g., 42 C.F.R. §§ 493.1105, 1239, 1407, 1251, and 1359.

31. In addition, Relator observed that Mimbres routinely failed to perform required quality control testing on instruments and equipment used in Mimbres' lab tests; such quality control testing was necessary to ensure that instruments, equipment, and procedures were consistently producing accurate and verifiable results.

32. Illustrative instances of Mimbres' failure to conduct required quality control testing in its lab are set forth below.

1. **Vitek 2 Microbial Identifier**

33. The Vitek 2 Compact System for Microbial Identification and Susceptibility Testing ("Vitek 2"), manufactured by bioMerieux, is a complex diagnostic device used in microbiology labs for identifying pathogenic microorganisms that cause disease in humans, and testing the susceptibility of the identified microorganism to various antibiotics. Results from the Vitek 2 are used to form a diagnosis and develop a proper treatment plan.

a. Verification Study

34. When Mimbres installed the Vitek 2 system in its microbiology lab in early 2008, it did not conduct required quality control testing – called a verification study – to ensure that the installed system functioned properly and was able to correctly identify the full range of microorganisms and antibiotic resistances within its reportable range. In addition, after its installation, Mimbres did not conduct ongoing quality control testing that was required to ensure that the Vitek 2 system continued to provide accurate and reliable results.

35. Under CLIA, when a lab installs a new FDA-approved test system such as Vitek 2, it must demonstrate that it can obtain results with the same level of accuracy and precision as set forth in the manufacturer's performance specifications for all microorganisms for which the test system will be used to report results. The laboratory is further required to document its performance of these initial quality control verification steps. See 42 C.F.R. §§ 493.1252, 1253.

36. BioMerieux's Operating Manual for the Vitek 2 sets forth a performance specification of 96.5% accuracy, and references the "most stringent inspecting agency's guidelines for frequency of identification product testing." Those standards are set forth by the Clinical and Laboratory Standards Institute ("CLSI") (formerly known as the National Committee for Clinical Laboratory Standards, or NCCLS) under standards M7-A6 ("Methods for

Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard") and M50-A ("Quality Control for Commercial Microbial Identification Systems; Approved Guidelines").

37. Under those standards, before reporting any patient results from the Vitek 2, Mimbres was required to verify the manufacturer's performance specifications by testing the new Vitek 2 in parallel with an established method of identification and susceptibility testing already in use in the microbiology lab and comparing the results to the performance specifications published by bioMerieux.

38. When Mimbres installed the Vitek 2 system, it did not document the completion of a verification study. Despite failing to verify the system's accuracy and reliability, Defendants put the system into regular use on patient specimens, greatly increasing the danger to patients of incorrect diagnoses and treatment.

b. <u>Antimicrobial Susceptibility Testing Cards</u>

39. The Vitek 2 is also used for antimicrobial susceptibility testing, which is done to determine which antibiotics are effective for the treatment of pathogenic organisms from a patient specimen. For antimicrobial susceptibility tests, manufacturer specification and CLSI guidance require laboratories to check each batch, lot number, and shipment of Vitek 2 Antimicrobial Susceptibility Testing Cards before, or concurrent with, initial use, using approved "control" organisms. Control organisms are known, isolated organisms used to ensure that the system can properly identify them. The Vitek 2 Antimicrobial Susceptibility Testing cards are a panel of antibiotics that the organisms are tested against to assess their level of resistance to various antibiotics. Quality control testing on Antimicrobial Susceptibility Testing Cards is done

to ensure that the Vitek 2, and its panel of antibiotics against which organisms are tested, function properly.

40. Quality control testing must also be performed each day of use unless the laboratory has demonstrated satisfactory quality control performance for conversion from daily (each day of use) to weekly quality control testing. See 42 C.F.R.§ 493.1261(b). In order to convert to weekly antimicrobial susceptibility quality control testing, the microbiology lab must test all applicable control strains for 20 or 30 consecutive test days and document results. No more than 1 out of 20 or 3 out of 30 results for each antimicrobial agent/organism combination may be outside the acceptable limits set forth in the manufacturer's documentation.

41. Mimbres did not conduct antimicrobial susceptibility quality control testing each day of use or verify that the control results were within established limits before reporting patient results. Mimbres did not qualify for streamlined weekly testing because it did not complete the 20 or 30-day required quality control process. Instead, the quality control logs within the Vitek 2 show that the control organisms were only tested for 14 days shortly after it was installed in early 2008, that out-of-control results occurred several times during that period, and that no further attempt to qualify for weekly quality control testing was done on the system. Nevertheless, Mimbres did not conduct daily testing. Indeed, when Relator began working at Mimbres, she was not instructed to perform daily testing, and she could not find any documentation demonstrating that someone in the laboratory was or had been conducting such ongoing quality control testing.

c. Identification Cards

42. CLIA also requires laboratories to substantiate the continued accuracy of the test system by checking each new batch, lot number and/or shipment of Identification Cards, which contain a panel of reagents, for positive and negative reactivity using control organisms. See 42 C.F.R. § 493.1261(a). Reagents contained in the Identification Cards are biochemicals that cause certain reactions when they interact with specific pathogenic microorganisms, allowing for the identification of pathogens contained in patient specimens. Quality control testing on the Identification Cards is done to ensure that the reagents are non-defective and can properly identify each pathogenic microorganism. The Vitek 2 uses Gram positive and Gram negative Identification Cards to identify various pathogenic microorganisms. The CLIA and CLSI standards referenced by the Vitek 2 Operating Manual require testing on each new batch, lot number and/or shipment of Identification Cards with multiple control organisms to demonstrate a positive and negative reaction for each biochemical test on the Identification Cards.

43. Mimbres did not conduct quality control testing on the Vitek 2 Identification Cards in accordance with manufacturer's instructions and CLIA requirements. Specifically, quality control testing on new lots of Vitek 2 Gram negative Identification Cards requires the testing of seven control organisms specified by BioMerieux, the Vitek 2 manufacturer; new lots of Gram positive Identification Cards require the testing of eight specified control organisms. Mimbres often tested only one control organism for each new lot or shipment of Gram positive and Gram negative Identification Cards. In addition, testing on those organisms sometimes produced errors. Mimbres did not stop reporting results until the problem was resolved and verified through additional testing; rather, Mimbres simply disregarded the errors and continued

to report patient results on the unverified lot number of Identification Cards and bill for such services.

44. Under streamlined quality control testing procedures, a lab could test only two bugs each for the Gram negative and Gram positive Identification Cards. Mimbres did not meet the manufacturer's requirements to conduct such testing, which require a lab to perform quality control testing on three consecutive lot numbers of Identification Cards from three different shipments that span three consecutive seasons, to assess seasonal variations in shipping conditions that could damage the reagents on the Identification Cards. Mimbres did not conduct such testing. In any event, even if Mimbres had qualified for streamlined testing, it did not conduct testing on the two control organisms specified for each Identification Card; instead, it tested on the few organisms it was able to grow and keep healthy for testing purposes.

45. Mimbres laboratory's failure to conduct quality control tests on the Vitek 2 machine when it was first installed and the failure to conduct ongoing quality control testing were violations of CLIA. Indeed, the Procedures Manual did not contain quality control procedures for, or even make mention of, the Vitek 2. All lab results produced by the Vitek 2 since its installation were not performed in accordance with required standards and are thus unverified and unreliable for use in patient diagnoses, and, in turn, unreimbursable by Medicare and Medicaid.

46. The Vitek 2 is the only microbial identification and susceptibility testing system used in the Mimbres lab; it was used for nearly all such tests done in the lab. The Vitek 2 produced approximately 25-30 lab test results per week that the Mimbres lab reported for patient diagnoses and treatment, and billed to medical providers including Medicare and Medicaid.

2. Culture Media and Reagents

47. Culture media, such as petri dishes containing agar (a solution usually consisting of sugar and other ingredients that provide "food" to microorganisms), are used to support the growth of pathogens. Culture media play a pivotal role in a microbiology laboratory. They are widely employed for isolation, identification and sensitivity testing of different pathogenic microorganisms. For example, a human specimen such as sputum (taken from the lungs) may be placed on a culture media in order to allow the microorganism contained in the sputum to grow; the characteristics of the larger sample grown on the culture media are then analyzed to identify the microorganism harming the patient. Quality of media directly affects the observations and inferences that can be drawn from the cultural characteristics of microorganisms. The meticulous performance of quality control procedures on culture media is necessary to ensure precision in reporting lab test results from such media.

48. The same is true of reagents, which, as discussed above, are biochemicals used to identify microorganisms. Defective or expired batches of reagents will not produce the chemical reaction expected to occur in the presence of a particular pathogen, and thereby result in misdiagnoses.

49. In violation of CLIA requirements, Mimbres did not conduct quality control testing on new lots of commercially purchased culture media and reagents used in identifying microorganisms for diagnosis and treatment.

50. Among the various media Mimbres used that require quality control testing are SSA, for the isolation of Group A Streptococcus in throat cultures to detect "strep throat"; Todd Hewitt Broth, used to isolate Group B Streptococcus in pregnant women (the most common

etiologic agent of neonatal sepsis and meningitis if not detected in the mothers vaginal/rectal specimen); MacConkey/Sorbitol, used on stool cultures to detect E. Coli 0157 (a deadly strain of E. Coli that has been responsible for fatal outbreaks around the country); and CHROMagar, used to detect MRSA, or Methicillin Resistant Staph Aureus, a highly resistant strain of Staphylococcus.

51. Mimbres usually purchased 5 to 10 boxes of each media at a time. The boxes in a shipment usually had the same lot number. Each box usually contained approximately 20 plates of the media.

52. Reagents used in Mimbres' lab that require quality control testing include Indole, Oxidase, Staph Aureus/Latex and Strep Grouping.

53. Under CLIA, a laboratory must conduct quality control testing on new lots of commercially purchased culture media and reagents to ensure their sterility and ability to support the growth of microorganisms and produce desired reactions. See 42 C.F.R. § 493.1256(e). In addition, CLIA requires laboratories to ensure that quality control testing on such products meet the manufacturer's performance specifications before reporting test results. See 42 C.F.R. § 493.1256(f). The manufacturer's performance specifications commonly incorporate CLSI guidance set forth in M22-A3 ("Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard").

54. For example, under the manufacturer's specifications for Beckton Dickinson's CHROMagar, one of the culture media used in the Mimbres microbiology lab, and under the CLSI guidance set forth in M22-A2, the media's performance in supporting growth must be checked by visually inspecting the culture media for signs of deterioration, and by inoculating a

representative sample of the media with pure cultures of microorganisms that produce known, desired reactions.

55. Mimbres did not conduct quality control testing on culture media and reagents that required it, including those identified above, and maintained no documentation of such testing. The failure to conduct such testing calls into doubt the results of every lab result generated from culture media and reagents in those lots.

56. Mimbres' failure to conduct required quality control testing on new lots of culture media and reagents impacts the results of nearly every patient result reported out of the lab. Culture media, in particular, are used as part of nearly every test performed in the microbiology lab. Patient specimens are placed on various culture media to help in their identification. Where observation of the culture media suggests pathogens, other testing such as use of the Vitek 2 is often performed. However, where observation of the culture media suggest no pathogenic growth, lab results reflecting normal flora – harmless, non-pathogenic microorganisms – will be reported back to the physician and no additional testing will be done. So, for example, a bad lot of culture media would not foster the proper growth of a pathogen; the lab would then report normal flora when, in fact, the patient may suffer from streptococcus, E. coli or other life-threatening pathogens.

57. Mimbres used approximately 200 culture media per week. In Relator's experience, receipt of a bad lot of culture media can occur as often as several times per year at a hospital of Mimbres' size, creating the possibility of hundreds of missed diagnoses each year.

3. Commercial Kit Tests

58. Medical laboratories commonly use commercially-prepared immunoassay tests, known as "kits," to identify specific pathogens or disorders. An immunoassay is a biochemical test that measures the presence or concentration of a substance in solutions that frequently contain a complex mixture of substances. They are commonly used to analyze biological liquids such as serum, stool, or urine for specific pathogens. Mimbres used immunoassay kit tests to identify the following pathogens: Clostridium difficile A and B toxin, Shiga Toxin, H. pylori, Campylobacter, and Rotavirus.

59. Consistent with the requirements for culture media, laboratories must conduct quality control testing on each new lot and/or shipment of commercial kits, using the external quality control testing material provided with the kit to ensure that the tests in that lot are capable of producing accurate results. See 42 C.F.R. § 493.1256. As with all quality control testing, documentation of such testing is required.

60. Mimbres routinely failed to conduct required quality control testing on new lots of commercial kits. Indeed, when Relator began working at Mimbres, she observed that the quality control log for commercial kit tests did not contain documentation reflecting that such testing had been performed for any of the lots of commercial kits in use at the time. Moreover, the Procedures Manual did not contain instructions for performing testing on some of the commercial kit tests, including Camplyobacter.

61. Relator informed Bessell and Johanna Gramer ("Gramer"), a Human Resources Director, about the failure to conduct such testing as soon as she learned about it, and began performing some of the testing herself. In addition, in early June 2010 she provided Gramer with the lot numbers of the commercial kits in use at the time and a copy of the quality control log

that did not contain documentation of quality control testing for those lot numbers. Neither Bessell nor Gramer took steps to resolve the issue.

4. Gram Stains

62. Gram staining, the most useful test in a lab's microbiology department, is a form of microscopic testing used in labs to help determine the identity of bacteria before other lab tests – that can often take several days – are completed. It is a differential staining procedure most commonly used for direct microscopic examination of specimens and bacterial colonies. Gram staining is used to divide bacteria into two main groups - Gram negative and Gram positive – in order to determine the antimicrobial drug treatment to be used.

63. Gram staining is done on a direct specimen such as sputum, which is smeared on a slide. The slide is then flooded with Crystal Violet, a stain that Gram positive bacteria retain and that appears deep blue or purple. The slide is then washed and flooded with a chemical so that any Gram positive bacteria do not lose the deep blue or purple colorization, and then washed and flooded with Safranin, a stain that is retained by Gram negative bacteria and appears pink. The slide is then placed under microscopic examination, where the Gram positive organisms will appear as blue cocci (round) or rods, and the Gram negative organisms will appear as pink cocci or rods. This gives the clinician an immediate idea of what the microorganism might be while it is growing on culture media, which often require several days to produce results. For example, Staphs are Gram positive cocci, and E. coli is a Gram negative rod; if you saw Gram positive lancet-shaped cocci in pairs, it is most likely Streptococcus Pneumoniae a common cause of pneumonia, septicemia and meningitis. These initial results from Gram staining allow physicians to begin a course of treatment before other testing is completed.

64. Mimbres routinely failed to conduct required quality control testing on the staining reagents used in the procedure, including Crystal Violet and Safranin, or on the Gram staining process itself as performed by lab personnel.

65. For Gram testing, a quality control slide is one with known Gram negative and Gram positive microorganisms on it, usually Staph Aureus and E. coli. Under CLIA, a laboratory must conduct quality control testing on Gram stains once a week. See 42 C.F.R. § 493.1261.

66. Mimbres' laboratory did not conduct weekly control testing on Gram stains, and did not have documentation reflecting the performance of such testing. Moreover, the stains used at Mimbres were expired, a violation of CLIA requirements. See 42 C.F.R. § 493.1252(d).

5. Blood Culture Analyzer

67. The BacT/Alert 3D, manufactured by bioMerieux, is an automated microbial detection system and blood culture analyzer used to detect microorganisms in blood. Blood from patients is placed into bottles containing nutrient media and placed in the BacT/Alert 3D for analysis.

68. The quantity of blood in the bottles is the single most important factor in the isolation of pathogens from blood. Under CLIA, based on the manufacturer's specifications and CLSI guidance set forth in M47-A ("Principles and Procedures for Blood Cultures; Approved Guideline"), for adults 20 mls of blood should be drawn and 10 mls should be placed into each of two bottles, for aerobic and anaerobic testing. For children up to six years old, a single pediatric bottle is used and one ml of blood must be drawn for each year of age. Failure to use

these required quantities of blood for blood culture analysis in the BacT/Alert 3D can dramatically reduce the chances of recognizing and identifying pathogens contained in blood.

69. During Relator's employment, Mimbres' laboratory routinely drew inadequate amounts of blood from adult patients. While analyzing results from the BacT/Alert 3D during her second week at Mimbres, Relator noticed that the Bac T/Alert 3D contained an unusually large number of pediatric bottles, which each hold approximately 3 mls of blood. She checked the demographics of each patient and found that 17 out of 18 pediatric bottles were being used for adult patients. The small amounts of blood in the pediatric bottles – in some instances as little as 1 or 2 mls – made it extremely unlikely that pathogens in the adult patients' blood would be detected, creating a significant possibility of harm to the patient, including death. For example, Septicemia, a disease process involving the growth of bacteria in the bloodstream, can cause death if not treated immediately.

70. Relator printed results from the BacT/Alert 3D demonstrating the inadequate blood samples and showed them to Bessell. Because of the grave implications of the violation, a memo was written to all lab personnel involved in drawing blood cultures and the violation stopped. However, Defendants did not notify physicians and affected patients of the improper testing, or relevant state officials, and did not return reimbursements from Medicare, Medicaid and other providers for such services.

71. The failure to draw adequate blood and to identify the problem as soon as it occurred reflects Mimbres' inadequate quality control procedures. Detailed instructions for performing blood culture analysis using the BacT/Alert 3D should have been included in the Procedures Manual and followed, but were not.

MIMBRES OFFICIALS IGNORED RELATOR'S CONCERNS AND INSTEAD RETALIATED AGAINST HER

72. Relator observed violations of CLIA within days of joining Mimbres. She immediately raised concerns to Bessell, the Lab Director at Mimbres. He told Relator to try to fix it; however, as discussed below, he undermined her efforts to do so.

73. Both the procedures set forth in the Procedures Manual and the actual practices of lab personnel were woefully inadequate and reflected numerous CLIA violations. Yet, Bessell, in his capacity as Lab Director, signed off on the Procedures Manual each year, including in January 2009 and January 2010.

74. Relator presented her concerns to Rivero in order to fix the lab's violations. Rivero was the other full-time Medical Technologist in the microbiology department at Mimbres and had worked at Mimbres since approximately January 2008. Specifically, Relator spoke to Rivero about the outdated Procedures Manual and the rampant failure to conduct required quality control testing on equipment, media, reagents, instruments and test systems. Rivero refused to take any action.

75. Relator informed Bessell about Rivero's lack of cooperation and reiterated her concerns about numerous CLIA violations in Mimbres' laboratory. Bessell did not take any actions to resolve the problems. Relator tried to present Bessell with evidence of the lab's inadequate procedures and lack of documentation, but Bessell refused to review it. Rather, he became irritated with Relator and told her that she was being disruptive by continuously raising issues to him.

76. In or around early June 2010, Relator spoke to Gramer, the Human Resources Director. Relator told Gramer about the violations she had found and Bessell and Rivero's

refusal to address the serious health and safety issues she had raised. Gramer said she would provide the information to Susan Noltie ("Noltie"), Mimbres' Corporate Compliance Officer. Two days later, Relator provided Gramer with whatever documentation she could about the violations, including copies of sections of the Procedures Manual and quality control logs that were incomplete and that did not include documentation of many of the tests that should have been performed in the lab. Relator did not hear back from Gramer or Noltie.

77. Several weeks after raising her concerns, Relator saw Noltie at a restaurant and told her that, in her opinion, the microbiology lab in particular needed to be shut down because of all of the violations in that department.

78. Rivero later falsified documents to make it appear that Defendants had conducted quality control testing that had not been done. For example, Rivero forged at least one and a half years of testing in the quality control log for Gram staining that had not been done. Relator informed Bessell, Gramer and others of Rivero's actions.

79. At the time Rivero falsified documents, a lab employee from a hospital in Artesia, New Mexico conducted a purported "inspection" of the lab; she reported that she found no issues. The inspection, deliberately conducted on a day when Relator was not working, was bogus: the Artesia employee was a friend of Bessell's, she was not a certified inspector, and she had no authority or responsibility to conduct lab inspections.

80. On June 27, 2010, Relator wrote a letter to William Quitmeyer ("Quitmeyer"), Mimbres' Chief Executive Officer, and provided copies to Bessell and Gramer. In her letter, she again cited the inadequate Procedures Manual and lack of quality control testing, as well as

Bessell's failure to address the problems. Relator did not receive any response from Quitmeyer or from anyone at his direction.

81. Throughout this period, Defendants continued to report test results from the Mimbres lab for patient diagnosis and treatment, and bill Medicare and Medicaid for such services.

82. After Relator's letter to Quitmeyer, Bessell and Rivero began to threaten and harass Relator. Bessell told Relator on a daily basis that if she did not quit, he would fire her. On one occasion, when Relator told Bessell that she could not find documentation reflecting that a verification study had been done on the Vitek 2 when it was installed, he became angry, stood inches from her face, and yelled that she had no business looking at past quality control and that she should stay out of it.

83. Rivero came in on one of his days off to further intimidate and harass Relator. He warned her about continuing to raise concerns with management. Relator went to Bessell while Rivero was yelling at her because she was frightened, but Bessell did nothing to stop the harassment. Relator filed a harassment complaint concerning the treatment to which she was being subjected.

84. On or about July 22, 2010, Relator was placed on paid administrative leave.

85. Shortly thereafter, a corporate compliance investigator from Defendant CHS conducted an inspection of the lab based on Relator's complaints that verified her allegations. Based on the investigation, the microbiology lab was shut down. However, nothing was done concerning deficiencies in the Procedures Manual and in quality control testing in other lab departments.

86. Defendants did not inform doctors and patients about the violations Relator had identified and that had resulted in shutting down a portion of the lab, despite the certainty of misdiagnoses and the potentially grave implications of such errors. In fact, CLIA regulations require that when errors occur, the lab must promptly inform the requesting physicians. See 42 C.F.R. § 493.1291(k).

87. Similarly, Defendants did not inform state and federal authorities or the Joint Commission of the violations, preventing inspectors from investigating and re-assessing the lab's qualification for a CLIA certificate. Finally, Defendants did not inform Medicare or Medicaid officials, or return reimbursements received for billing associated with lab services performed in blatant violation of CLIA requirements.

88. Relator was allowed to return to work in February 2011. However, she was told that she would have to work a different, less desirable, shift. In light of the schedule change, and the treatment to which she had been subjected, Relator had no choice but to quit.

THE FALSE CLAIMS

89. CLIA's comprehensive quality requirements are intended to ensure safe and reliable lab testing in medical laboratories across the United States. Medical providers are prohibited from seeking payments from Medicare and Medicaid for laboratory services that are provided in violation of those quality requirements. When a medical provider performs laboratory testing in violation of CLIA but nevertheless seeks payments from Medicare or Medicaid for those lab tests, it is liable under the False Claims Act for reimbursement of the payments.

90. As a result of the gross violations of CLIA in the Mimbres lab, described above, Defendants received millions of dollars in payments for laboratory services that placed patients' lives at risk by failing to meet minimum quality standards. Defendants submitted false claims to federal and state government agencies, which resulted in the payment by Medicare and Medicaid of reimbursements for ineligible lab services.

91. Defendants' lab was required to submit to periodic inspections and re-certifications under CLIA, including the re-certification process that occurred in October 2009. Maintaining CLIA certification was necessary to perform lab testing and bill for such services. Defendants misled the Joint Commission and other inspectors through the use of false information, including doctored records, and material omissions, thereby causing the inspectors to allow the Mimbres lab to retain CLIA certification when, in fact, it was materially non-compliant. As a result, Mimbres' CLIA certification was fraudulently induced in violation of 31 U.S.C. § 3729 (a)(1)(A-B). Moreover, RRC was able to continue to bill Medicare and Medicaid for lab services only as a result of this same fraud. Accordingly, the subsequent Medicare and Medicaid bills are also false claims in violation of 31 U.S.C. § 3729 (a)(1)(A-B).

COUNT I – Federal False Claims
31 U.S.C. §§ 3729 (a)(1)(A-B,G)

92. Relator Hansen incorporates each paragraph of this Complaint as if fully set forth herein.

93. Through the above-described conduct, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729.

94. Through the above-described conduct, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get false or fraudulent claims paid or approved in violation of 31 U.S.C. § 3729.

95. Through the above-described conduct, Defendants knowingly made, used, or caused to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money to the United States in violation of 31 U.S.C. § 3729.

WHEREFORE, Relator Sally Hansen respectfully demands:

A. Judgment in favor of herself and the United States of America and against Defendants in the amount of $11,000 for each false claim and false statement that Defendants submitted to Medicare together with treble the amount of payment received and/or costs avoided;

B. Judgment awarding Relator 30% of any recovery;

C. Judgment awarding the costs and reasonable attorneys fees incurred in prosecuting this action; and

D. Any other relief to which she may appear entitled.

COUNT II – New Mexico Medicaid False Claims Act and Fraud Against Taxpayers Act New Mexico Statutes §§ 27-14-3 and 44-9-3

96. Relator Hansen incorporates each paragraph of this Complaint as if fully set forth herein.

97. Through the above-described conduct, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval, and/or made, used, or caused to be made or used, a false record or statement to obtain payment or approval on false or fraudulent claims, and/or made, used, or caused to be made or used, a false record or statement to

conceal, avoid or decrease an obligation to pay or transmit money to the state, in violation of New Mexico Statutes § 27-14-4 and § 44-9-3.

WHEREFORE, Relator Sally Hansen respectfully demands:

A. Judgment in favor of herself and the State of New Mexico and against Defendants in the amount of $10,000 for each false claim and false statement that Defendants submitted to Medicaid together with treble the amount of payment received and/or costs avoided;

B. Judgment awarding Relator 30% of any recovery;

C. Judgment awarding the costs and reasonable attorneys fees incurred in prosecuting this action; and

D. Any other relief to which she may appear entitled.

COUNT III – Retaliation Under Federal False Claims Act
31 U.S.C. §§ 3729 (h)

98. Relator Hansen incorporates each paragraph of this Complaint as if fully set forth herein.

99. Because of her lawful acts to stop Defendants from defrauding the government as alleged herein, Defendants retaliated against Relator Hansen in the terms and conditions of her employment by placing her on administrative leave and constructively discharging her by changing her schedule.

100. Under 31 U.S.C. § 3730(h), Defendants are liable to Hansen for two (2) times her back pay plus interest and special damages, including but not limited to attorneys' fees and litigation costs.

WHEREFORE, Relator Hansen respectfully demands:

A. Judgment in favor of herself and against Defendants, awarding two times her back pay, plus special damages;

B. Judgment awarding the costs and reasonable attorneys fees incurred in prosecuting this action; and

C. Any other relief to which she may appear entitled.

COUNT IV – Retaliation Under New Mexico Medicaid False Claims Act and Fraud Against Taxpayers Act
New Mexico Statutes §§ 27-14-12 and 44-9-11

101. Relator Hansen incorporates each paragraph of this Complaint as if fully set forth herein.

102. Because of her lawful acts to stop Defendants from defrauding the government and in furthering a false claims action, as alleged herein, Defendants retaliated against Relator Hansen in the terms and conditions of her employment by placing her on administrative leave and constructively discharging her by changing her schedule.

103. Under New Mexico Statutes §§ 27-14-12 and 44-9-11, Defendants are liable to Hansen for two (2) times her back pay plus interest and special damages, including but not limited to attorneys' fees and litigation costs.

WHEREFORE, Relator Hansen respectfully demands:

A. Judgment in favor of herself and against Defendants, awarding two times her back pay, plus punitive and special damages;

B. Judgment awarding the costs and reasonable attorneys fees incurred in prosecuting this action; and

C. Any other relief to which she may appear entitled.

JURY DEMAND

The United States of America and the State of New Mexico, on relation of Ms. Hansen, hereby demand trial by jury on all issues so triable.

Respectfully submitted,

LOEVY & LOEVY

By: Electronically Signed 06/27/11
Arthur Loevy
Michael Kanovitz
Jon Loevy
Anand Swaminathan
312 North May Street, Suite 100
Chicago, IL 60607
Phone: (312) 243-5900
Fax: (312) 243-5902

ROTHSTEIN, DONATELLI, HUGHES,
DAHLSTROM, SCHOENBURG & BIENVENU, LLP

By: Electronically Signed 06/27/11
Robert R. Rothstein
Brendan K. Egan
1215 Paseo de Peralta
Post Office Box 8180
Santa Fe, NM 87504-8180
Phone: (505) 988-8004
Fax: (505)982-0307

Attorneys for Plaintiffs

S:\Bob\7962\Plead\Complaint.docx